

WE CLAIM:

1. A method of detecting and quantifying EGFRvIII in a
5 mammal, comprising performing an ELISA specific for EGFRvIII with a
biological sample from said mammal.

2. The method of **Claim 1**, wherein the biological sample is at
least one of the group of urine, serum, plasma, CSF, amniotic fluid, breast
10 secretions, lung sputum, or tumor cell extracts.

3. A method of detecting cancer in a mammal, comprising
performing an ELISA specific for EGFRvIII with a biological sample from
said mammal.
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4. The method of **Claim 3**, wherein the biological sample is at
least one of the group of urine, serum, plasma, CSF, amniotic fluid, breast
secretions, lung sputum, or tumor cell extracts.

5. The method of **Claim 3**, wherein said cancer is at least one of
20 the group of breast cancer, adenocarcinoma, squamous lung cancer,
gastrointestinal cancer, renal cell cancer, bladder cancer, glioma,
gynecological carcinoma, or prostate cancer.

6. A method of selecting a mammal with cancer for novel
25 mutant EGF-directed anticancer therapies from at least one of the group
of a vaccine, an antibody-toxin conjugate, or EGFRvIII-specific tyrosine
kinase inhibitors, comprising performing an ELISA specific for EGFRvIII
with a biological sample from said mammal, analyzing results of said
30 ELISA, and selecting at least one of the group of said mutant EGF-
directed anticancer therapies.

7. The method of **Claim 6**, wherein the biological sample is at least one of the group of urine, serum, plasma, CSF, amniotic fluid, breast secretions, lung sputum, or tumor cell extracts.

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8. An ELISA for the sensitive detection of wild type and/or EGFRvIII in a mammalian sample of urine, serum, plasma, CSF, amniotic fluid, breast secretions, lung sputum, tumor cell extracts, or any extracellular or cellular fluids.

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9. A method of detecting a preneoplastic lesion in a mammal, comprising performing an ELISA specific for EGFRvIII with a biological sample from said mammal.

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10. The method of **Claim 9**, wherein the preneoplastic lesion is Barrett's esophagus.

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11. A method of detecting benign prostatic hyperplasia in a mammal, comprising performing an ELISA specific for EGFRvIII with a biological sample from said mammal.

12. A method of generating antibodies specific for EGFRvIII, comprising:

25 preparation of an antibody against the mutant EGF receptor by immunizing a mammal with at least one of a mutant receptor protein, an epitope of said mutant receptor protein, a sequence that mimics said epitope, or DNA encoding said mutant receptor protein or epitope;

obtaining a high titer antibody preparation from said mammal, said antibody preparation recognizing mutant EGF and wild type (wt) receptor;

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pooling bleeds from said mammal, concentrating and partially purifying said bleeds by precipitation;

obtaining a pellet from said precipitation and dialyzing said pellet;

and

passing said (antibody preparation) dialyzed pellet over an affinity matrix column (with said epitope) and eluting antibodies from said column to obtain antibodies specific for EGFRvIII.

13. The method of **Claim 12**, wherein said epitope comprises EKKGNVYVV (SEQ ID NO:5), a fragment of said sequence, or a modification of said sequence.

14. The method of **Claim 12**, wherein said epitope comprises LEEKKGNYVVTDH (SEQ ID NO:1), a fragment of said epitope, or a modification of said epitope.

15. The method of **Claim 12**, wherein said epitope comprises KGN (SEQ ID NO:6) or a modification of said epitope.

16. The method of **Claim 12**, wherein said epitope comprises LEEKKC (SEQ ID NO:2), a fragment of said epitope, or a modification of said epitope.

17. The method of **Claim 12**, wherein said epitope comprises EKK (SEQ ID NO:7) or a modification of said epitope.

18. The method of **Claim 12**, wherein said epitope comprises NYVVTDH (SEQ ID NO:8), a fragment of said epitope, or a modification of said epitope.

19. The method of **Claim 12**, wherein said epitope comprises NYV (SEQ ID NO:9) or a modification of said epitope.

20. A method of generating antibodies specific for EGFRvIII, comprising:

preparation of an antibody against the mutant EGF receptor by
immunizing a mammal with at least one of a mutant receptor protein, an
epitope of said mutant receptor protein, a sequence that mimics said
5 epitope, or DNA encoding said mutant receptor protein or epitope;
obtaining serum from said; and
passing said serum over an affinity matrix column and eluting
antibodies from said column to obtain antibodies specific for EGFRvIII.

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